

Remarks/Argument

Claims 6-11, 14, and 16-21 are pending in the application. Claims 16-21 have been withdrawn. Claims 6-11 and 14 have been rejected.

Claim Rejections – 35 U.S.C. §102

Claims 6, 7, 8, 10 and 11 remain rejected under 35 U.S.C. 102(b) as anticipated for reasons already made of record. Claim 6, from which the remaining claims depend, has been amended to incorporate the transition phrase “consisting of,” rather than “comprising” or “consisting essentially of.” As Applicant has previously pointed out, the compositions of Moussa rely upon additional solubilizing agents.

Claim Rejections – 35 U.S.C. §103

Claims 6-11 and 14 have again been rejected under 35 U.S.C. 103(a) as obvious in view of the combined teachings of Burnside (U.S. 5,824,638 and U.S. 5,883,103), Moussa (WO 99/29300) and Roy. Applicants have claimed oil-in-water emulsions, while Burnside describes methods for forming water-in-oil emulsions. Moussa describes the use of a variety of surfactants for solubilizing a pharmaceutical formulation to form self-emulsifying concentrates. Moussa indicates that additional solubilizers are added to compositions in which TPGS and linoleic acid are ingredients. Applicants have discovered that if linoleic acid is used in conjunction with TPGS, the additional solubilizers are not necessary. Claim 6 has been amended to exclude additional solubilizers, as the combination of TPGS and linoleic acid is sufficient to provide the desired formation of an oil-in-water emulsion as provided for the in the present claims.

Claim Rejections – 35 U.S.C. §112

Claims 6-11 and 14 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite because of the term “essential fatty acids.” Unless specifically stated as related to other species, the term “essential fatty acids” is generally considered, by those of skill in the art of pharmaceutical formulation to which the invention pertains, to mean those fatty acids that are considered essential to humans. Applicant has attached to this response a copy of a page from Dorland’s Medical Dictionary, 18th edition, 1994 (W.B. Saunders, publisher), page 612, which defines an essential fatty acid as “any fatty acid that cannot be synthesized by the human body and must be obtained from dietary sources.” MedicineNet.com (<http://www.medterms.com/script.main/art.asp?articlekey=11349>) also defines an essential fatty acid as “[a]n unsaturated fatty acid that is essential to human health, but cannot be manufactured in the body.”

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 11, 2010.



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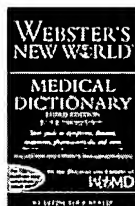
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Definition of Essential fatty acid



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Essential fatty acid: An unsaturated fatty acid that is essential to human health, but cannot be manufactured in the body. There are three types of essential fatty acids (EFAs): arachnoidic acid, linoleic acid, and linolenic acid. When obtained in the diet, linoleic acid can be converted to both arachnoidic and linolenic acid. It is commonly found in cold-pressed oils, and is particularly high in oils extracted from cold-water fish and certain seeds. Recent research has explored the role of EFAs in the nervous system health. Supplementation with certain EFOs appears to be useful as a treatment for certain neurological disorders. However, arachnoidic acid may lower the seizure threshold. For that reason, always consult a knowledgeable physician before starting a program of EFA supplementation.

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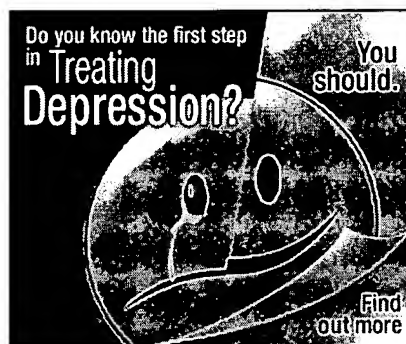
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fasciodesis

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fatty

known but frequently it occurs following strenuous exercise. Called also *Shulman's syndrome*.

exudative calcifying f., calcinosis.

intravascular f., a variant form of nodular fasciitis occurring in small to medium sized arteries and veins, usually in infants or young children.

necrotizing f., a fulminating group A streptococcal infection beginning with severe or extensive cellulitis that spreads to involve the superficial and deep fascia, producing thrombosis of the subcutaneous vessels and gangrene of the underlying tissues. A cutaneous lesion usually serves as a portal of entry for the infection, but sometimes no such lesion is found. Called also *gangrenous* or *necrotizing erysipelas*.

nodular f., a benign reactive proliferation of fibroblasts occurring as a rapidly growing nodular mass in the subcutaneous or deep somatic tissues, particularly of the upper extremities, usually in young adults or adults; histologically it closely resembles sarcoma. The term is sometimes used broadly to encompass variant forms such as proliferative fasciitis. Called also *pseudosarcomatous f.*

perirenal f., retroperitoneal fibrosis.

proliferative f., a benign reactive proliferation of fibroblasts in subcutaneous tissues, resembling nodular fasciitis but characterized also by basophilic giant cells resembling ganglion cells or rhabdomyoblasts; it usually occurs in the skeletal muscles in older adults. See also *nodular f.*

pseudosarcomatous f., nodular f.

fasciodesis (fas'e-od'ə-sis) [L. *fascia* + Gr. *desis* binding] the operation of suturing a fascia to skeletal attachment.

Fasciola (fə-si'ə-lə) [L. *fasciola* a band] a genus of flukes.

F. cer'vi, former name for *Paramphistomum cervi*.

F. gigan'tica, the giant liver fluke of Africa, Asia, and Hawaii, which occasionally infects man.

F. hepa'tica, the common liver fluke of sheep, oxen, goats, horses, and other herbivorous animals. It is occasionally found in the human liver, where it may cause dangerous symptoms by obstructing the biliary passages and by invasion of the liver parenchyma. Several snails of the genus *Lymnaea* act as invertebrate hosts. Called also *Distoma hepaticum*.

F. hetero'phyes, *Heterophyes heterophyes*.

F. mag'na, *Fascioloides magna*.

fasciolar (fə-si'ə-lər) pl. *fasciolar* [L., dim. of *fascia*] 1. a small band or striplike structure. 2. a small bandage.

f. cine'rea, *f. cine'rea cin'gull*, *gyrus fasciolaris*.

fasciolar (fah-si'ə-le) [L.] genitive and plural of *fasciola*.

fasciolar (fə-si'ə-lər) pertaining to a fasciola.

Fasciolotia (fas'e-o-let'ə) a genus of parasitic flukes.

F. illoca'na, *Echinostoma ilocanum*.

fascioliasis (fas'e-o-li'ə-sis) infection with *Fasciola hepatica* or *F. gigantea*.

Fascioloides (fas'e-o-loi'dēz) a genus of flukes.

F. mag'na, the large American liver fluke, a trematode found in the liver and lungs of herbivorous animals in North America; formerly called *Fasciola magna*.

fasciolopsia (fas'e-o-lop-si'ə-sis) the state of being infected with flukes of the genus *Fasciolopsis*.

Fasciolopsis (fas'e-o-lop'sis) [*fasciola* + Gr. *opsis* appearance] a genus of trematode worms.

F. bus'ki, a trematode worm found in the small intestine of residents in many parts of Asia. It is the largest of the intestinal flukes, and may cause nausea, diarrhea, and a malabsorption syndrome if present in large numbers. The intermediate hosts are the snails *Planorbis coenosus* and various species of *Segmentina*. Other names given this species are *F. fuelleborni* from Calcutta and Egypt, *F. goddardi* and *F. spinifera* from China, and *F. rathouisi* from Asia. Formerly called *Distoma buski*.

fascioplasty (fash'e-o-plas'te) plastic operation on fascia.

fasciorraphy (fash'e-or'ə-fe) [*fascia* + Gr. *rhaphe* suture] suture of lacerated fascia.

fasciotomy (fash'e-ot'ə-me) [*fascia* + Gr. *temnein* to cut] surgical incision or transection of fascia.

fascitis (fə-si'tis) fasciitis.

fast (fast) [A.S. *faest* firm; *faestan* to abstain from food] 1. immovable, or unchangeable; resistant to the action of a specific drug, stain, or destaining agent, as in acid-fast. 2. abstention from food.

fastidious (fas-tid'e-əs) in bacteriology, a microorganism having complex nutritional or cultural requirements for growth.

fastidium (fas-tid'e-əm) [L.] loathing, disgust.

f. ci'bi, loathing of food.

f. po'tus, loathing of drink.

fastigium (fas'ti-ga'təm) [L.] pointed; sharpened to apex.

fastigial (fas-tij'e-əl) of or pertaining to the fastigium.

fastigium (fas-tij'e-əm) [L. "gable end"] 1. the highest point of the fourth ventricle of the brain, at the junction between superior medullary velum and the nodulus. 2. the acme, or point, as of a fever.

fastness (fast'nəs) the quality, in bacteria, of being resistant to action of specific stains or inhibitors.

fat (fat) 1. adipose tissue; a white or yellowish tissue which soft pads between various organs of the body, serves to smooth out bodily contours, and furnishes a reserve supply of energy. 2. an ester of glycerol with fatty acids, usually oleic, myristic, stearic, or stearic acid; triglyceride; neutral fat.

bound f., masked f.

brown f., brown adipose tissue.

chyle f., fat in the form of an extremely fine emulsion taken up by the lymphatics of the intestine.

corpse f., adipocere.

fetal f., a term sometimes used in pathology to refer to adipose tissue.

grave f., adipocere.

masked f., fat that can be detected in a cell or tissue by chemical methods but is not revealed by staining methods; called also *bound f.*

milk f., the suspension in milk which tends to separate from cream.

molecular f., fat occurring in fine specks within the cells.

moruloid f., mulberry f., brown adipose tissue.

neutral f., see *fat* (def. 2).

paraneuric f., paraneuric f., corpus adiposum paraneuric.

perineuric f., perineuric f., capsula adiposa renis.

polyunsaturated f., a fat containing polyunsaturated fatty acids.

saturated f., a fat containing saturated fatty acids.

unsaturated f., a fat containing unsaturated fatty acids.

wool f., anhydrous lanolin.

wool f., hydrous, lanolin.

wool f., refined, anhydrous lanolin.

fatal (fa'tal) causing death; deadly; mortal; lethal.

fate (fāt) [L. *fatum* what is ordained by the gods] 1. a disposition or decreed outcome; see also *fate map*, under pharmacology, the intermediate and ultimate disposition in the body.

prospective f., the development normally achieved by the zygote or early embryo when there is no interference.

fatigability (fat'ig-a-bil'i-ty) (fat'ig-a-bil'i-te) easy susceptibility to fatigue.

fatigue (fā-tēg') [Fr.; L. *fatigatio*] 1. a state of increased and decreased efficiency resulting from prolonged or exertion; loss of power or capacity to respond to stimulation; gradual fracturing of a material due to repetitive or cyclic stress.

battle f., post-traumatic stress disorder.

combat f., post-traumatic stress disorder.

pseudocombat f., a term applied to psychiatric combat whose functional impairment is attributed to preexisting anxiety disorder rather than to reaction to combat stress.

stimulation f., an increase in the threshold of a neural element to repeated stimulation.

fat-ty (fat'e) pertaining to or characterized by fat.

fat-ty acid (fat'e) any straight chain monocarboxylic acid, especially those naturally occurring in fats. Fatty acids are classified as saturated or unsaturated; the latter are further classified as saturated or monounsaturated. The absolute and relative levels of the various fatty acids consumed have been linked with lipid levels, atherosclerosis, and coronary artery disease; accompanying table and illustration.

essential f.a., any fatty acid that cannot be synthesized in human body and must be obtained from dietary sources; leucic acid and linolenic acid.

free f. a's (FFA), nonesterified fatty acids.

monounsaturated f.a's, unsaturated fatty acids containing a double bond; they occur predominantly as oleic acid, olive, and canola oils. Monounsaturated fatty acids have been shown to reduce low-density lipoprotein levels and thus cholesterol level.

n-3 f.a's, ω -3 f.a's.

nonesterified f. a's (NEFA), the fraction of plasma fatty acids not in the form of glycerol esters. Called also *free fatty acids* because they are transported complexed with albumin. **ω -3 f.a's**, **omega-3 f.a's**, unsaturated fatty acids in which the double bond closest to the methyl (omega) terminus of the chain occurs at the third carbon from that end; they are present in animal fats and some vegetable oils. These fatty acids can